Exhibit F

Exhibit E

Nov. 4, 2015
Letter to FDA

ACOG
THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

Executive Vice President & Chief Executive Officer
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November 4, 2015

Robert M. Califf, MD, Deputy Commissioner for Medical Products and Tobacco
Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research
Food and Drug Administration
10902 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Califf and Woodcock:

On behalf of the American Congress of Obstetricians and Gynecologists (ACOG), an organization representing 58,000 physicians and partners in women's health, I would like to present our recommendations regarding the safety, effectiveness, and use of mifepristone. We hope this information will be useful to FDA in any future deliberations regarding revisions to the drug label, Risk Evaluation and Mitigation Strategy (REMS), and Elements To Assure Safe Use (ETASU).

Since FDA approval in 2000, mifepristone has been used by women over 2.5 million times as a safe, effective method of pregnancy termination. As outlined in the enclosed Committee Opinion #613, ACOG supports access to safe, legal abortion services as a necessary component of women's health care, supports the availability of high-quality reproductive health services for all women, and is committed to improving access to abortion. As our knowledge regarding mifepristone advances, we believe its labeling, REMS, and ETASU have become outdated and have limited women's access to safe, effective abortion care.

ACOG supports evidence-based regimens for provision of medication abortion services, as outlined in the enclosed Practice Bulletin #143. These evidence-based regimens have improved medication abortion in terms of expense, safety, speed, and adverse effects. Based on efficacy and the adverse effect profile, evidence-based protocols for medication abortion are superior to the FDA-approved regimen.

Regimens that use low doses of mifepristone (200 mg) have similar efficacy and lower costs compared with those that use mifepristone at 600 mg. Vaginal, buccal, and sublingual routes of misoprostol administration increase efficacy, decrease continuing pregnancy rates, and increase the gestational age range for use as compared with the FDA-approved regimen. ACOG supports efforts to align FDA labeling for mifepristone with evidence-based regimens.

In addition, ACOG would fully support the following changes to the current label, consistent with ACOG recommendations outlined in Practice Bulletin #143:

1. The drug should be indicated for use in medical abortions up to 70 days of gestation

   Although the method is most commonly used up to 63 days of gestation, the treatment is also effective after 63 days gestation[i].

2. The location where the patient should take these drugs should not be restricted

   There is no clinical justification for restrictions or regulations regarding the location of mifepristone or misoprostol ingestion or administration.

3. An in-person visit should not be mandated for follow-up assessment

   Follow-up after medication abortion is important, although an in-clinic evaluation is not always necessary.

4. Any licensed healthcare provider should be able to prescribe the drug, not just physicians

   Medication abortion can be provided safely and effectively by nonphysician clinicians.

In addition to the above recommendations, ACOG finds evidence regarding the safety of the drug over the past 15 years of use in the United States to be a compelling argument for the removal or substantial modification of the Risk Evaluation and Mitigation Strategy (REMS) and Elements to Assure Safe Use (ETASU) for mifepristone[ii]. These requirements are inconsistent with requirements for other drugs with similar or greater risks and serve as barriers to access without demonstrated improvements to patient safety or outcomes. Prescription access to medication abortion has been shown to improve access to care, and could also facilitate expansion of telemedicine models of provision that have been shown to increase access, particularly for women in rural areas.[iii] [iv] [v]

ACOG opposes regulations or restrictions that are inappropriately unique to the provision of abortion and that mandate procedures and care that are not evidence-based. The safety record of this drug does not warrant restrictions such as provider certification, dispensing of the drug in specific locations, or specified patient consent. A standard clinical license should be sufficient to ensure that a practitioner meets qualifications for prescribing mifepristone. Mandating the location where the drug is to be dispensed has no bearing on risk. The requirement that patients sign an FDA-approved agreement before receiving mifepristone is inconsistent with requirements for other drugs with similar or greater risks. In line with its safety record and to improve access, we recommend that mifepristone be made available in retail pharmacies like other prescription drugs, without unique provider certification or patient consent requirements.

Thank you for your consideration. We are available to answer any questions you may have regarding these issues.

Sincerely,

Hal C Lawrence MD

Hal C. Lawrence, III, MD, FACOG
Executive Vice President and CEO

[i] Abbas D, Chong E, Raymond EG. Outpatient medical abortion is safe and effective through 70 days gestation. Contraception 2015;92:197-9.
[ii] Cleland K, Smith N. Aligning mifepristone regulation with evidence: driving policy change using 15 years of excellent safety data. Contraception 2015;92:179-181.
[iii] Grossman D, Goldstone P. Mifepristone by prescription: a dream in the United States but reality in Australia. Contraception 2015; 92:186–189.
[iv] Grossman D, Grindlay K, Buchacker T, Lane K, Blanchard K. Effectiveness and acceptability of medical abortion provided through telemedicine. Obstet Gynecol 2011; 118:296–303.
[v] Grossman DA, Grindlay K, Buchacker T, Potter JE, Schmertmann CP. Changes in service delivery patterns after introduction of telemedicine provision of medical abortion in Iowa. Am J Public Health 2013; 103:73–8.